2 Flavours: the Legal Framework

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2.1
Definitions

Flavourings are a major category of ingredients intentionally added to food and feeding stuff. Flavourings are concentrated preparations with the primary purpose to impart flavour except for substances that have an exclusively sweet, sour or salty taste. They are added in small amounts to food or feeding stuff but are not intended to be consumed as such.

Flavourings may contain flavouring substances, flavouring preparations, process flavourings, smoke flavourings and flavouring adjuvants.

Flavouring substances are chemically defined substances with flavouring properties. There are three different categories of flavouring substances defined in the definitions of the IOFI Code of Practice and EU Flavour Directive 88/388/EEC [1, 2]:

1. Natural flavouring substances
2. Nature-identical flavouring substances
3. Artificial flavouring substances

Flavouring preparations are natural complexes used because of their flavouring properties. They contain flavouring constituents and they are obtained by appropriate physical, microbiological or enzymatic processes from foodstuffs or other material of vegetable or animal origin, either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation).

Process flavourings means products which are obtained according to good manufacturing practices by heating a mixture of ingredients to a temperature not exceeding 180 °C for a period not exceeding 15 min , the ingredients themselves not necessarily having flavouring properties, and at least one of which contains nitrogen (amino) and another is a reducing sugar.

Smoke flavourings means smoke extracts used in traditional foodstuff smoking processes. The EU Regulation on smoke flavourings subdivides them into four categories:

1. ‘Primary smoke condensate’ shall refer to the purified water-based part of condensed smoke and shall fall within the definition of ‘smoke flavourings’.

2. ‘Primary tar fraction’ shall refer to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and shall fall within the definition of ‘smoke flavourings’.
3. ‘Primary products’ shall refer to primary smoke condensates and primary tar fractions.
4. ‘Derived smoke flavourings’ shall refer to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods.

Flavouring adjuvants are foodstuffs, food additives, other food ingredients or processing aids which are necessary to ensure the safety and quality of flavourings and to facilitate the production, storage and intended use of flavourings.

Flavouring adjuvants may also include flavour modifiers.

2.2
Legal Positions

In the following, the regulations on flavourings of three major regions are presented. Several other countries have similar legal regulations or accept flavourings produced according to these regulations. One major difference is the general classification of flavourings. In some countries, flavourings are classified as food additives, like in the USA or Japan. In other regions, flavourings are considered to be a special type of foodstuff, like in the EU.

2.2.1
Current Situation in the EU

In 1988 the “Council Directive of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production” was published. Together with the amending Directive 91/71/EEC regulating the labelling of flavourings for end consumers, this Directive defined the categories of flavouring ingredients, purity criteria and maximum levels for certain “biological active principles” (BAPs). With this Directive the frame for following specific regulations was established [2, 3].

Two specific Regulations mentioned in the indent of EU Flavour Directive 88/388/EEC have been established.

1. The EU Regulation on smoke flavourings which was published in 2003 [4]. The major subject of this Regulation is to establish:
   (a) A Community procedure for the evaluation and authorisation of primary smoke condensates and primary tar fractions for use as such in or on foods or in the production of derived smoke flavourings for use in or on foods.

(b) A Community procedure for the establishment of a list of primary smoke condensates and primary tar fractions authorised to the exclusion of all others in the Community and their conditions of use in or on foods.
The evaluation of those primary products will be carried out by the respective panels of the European Food Safety Authority (EFSA).
After finishing the evaluation procedures a positive list of primary smoke condensates, including purity criteria and maximum levels for contaminants, will be established in the EU.

2. The EU Regulation on food additives necessary for storage and use of flavourings, including respective conditions for their use, has been established. Following several years of intensive discussion and several drafts, Directive 2003/114/EC amending Miscellaneous Directive 95/2/EC was been published on 22 December 2003 [5, 6].

The Directive states that the levels of additives present in flavourings should be the minimum required to achieve the intended purpose. Flavouring adjuvants should not have a remaining technological function in the final foodstuff. With regard to this requirement, the possibility of the “carryover” of additives used in flavourings is especially mentioned in the Directive.

If the additive still has its technological function in the final food, labelling of this additive will be necessary for the final foodstuff as well.

In addition, the sixth indent of this Directive mentions that in accordance with the provisions of the EU Flavour Directive, quantitative labelling of each component which is subject to quantitative limitation, expressed either numerically or by *quantum satis* principles, is required for the flavour.

Following article 5 of the EU Flavour Directive, EU Regulation 2232/96 defined the basic rules for the use of flavouring substances for foodstuffs in the EU. In addition, it lays down a procedure for establishing a positive list for flavouring substances in the EU [7].

The procedure for evaluation was published as Commission Regulation 1565/2000 [10].

In 1998 the EU Commission within the Commission Decision 199/217/EEC published an inventory of flavouring substances used in the EU. This inventory (including its amendments) lists most of the flavouring substances which are subject to evaluation, leading to a positive list of flavouring substances to be used in foodstuffs in the EU [8].

The agreed timetable according to Commission Regulation 622/2002 mentioning the finalisation by 2005 has been postponed to 2007/2008 because the evaluation could not been finalised within the expected period [9].

In the meantime the existing national regulations of EU member states regarding flavouring substances are still in force. These existing national regulations show an unlimited permission of use for natural and nature-identical flavouring substances as defined in the EU Flavour Directive in all EU member states except Italy. Italy has kept a specific limitation for seven nature-identical flavouring substances.

Regarding artificial flavouring substances, four EU member states (Germany, Italy, Spain and the Netherlands) have specific positive lists with use levels, whereas all other EU member states permit all artificial flavouring substances suitable for human consumption.

With regard to the flavouring preparations, some EU countries have negative lists for plant materials which should not be used for production of flavouring preparations.

The labelling requirements for flavourings in the EU are laid down in EU Flavour Directive 88/388/EEC for the flavourings themselves and in EU Directive 91/72/EEC concerning the designation of flavourings in the list of ingredients of the final foodstuff.

It is required to use the word "flavouring" or a more specific name or description of the flavouring.

The word "natural" or a word of similar meaning may only be used if the flavouring ingredients are exclusively natural flavouring substances or flavouring preparations. Mentioning the flavouring source together with the word "natural" is only permitted if the flavouring ingredients have been isolated solely or almost solely from this source [2, 3].

2.2.2
Expected Regulations on Flavourings in the EU in the Future

The EU Commission is currently preparing a revision of the EU Flavour Directive. The publication of the finalised version for submission to the Council and the European Parliament is expected for 2006. In order to reduce the number of Regulations and Directives, the EU Commission will present a Regulation combining the Additive Directive, the revision of the Flavour Directive and a new Enzyme Regulation in one framework regulation of those "food improving agents".

Summarising the previous discussion and drafts, the new EU Flavour Regulation will show some new definitions of flavouring ingredients, like "flavour precursors" and "other flavourings". Within the definition of flavouring ingredients, it shall be distinguished between flavouring ingredients derived from food and material of vegetable or animal origin not consumed as food (non-food). Such flavouring ingredients derived from non-food material will be evaluated and will need explicit authorisation. The respective principles for authorisation and the procedures will be implemented in the new regulation. Also the existing regulations for genetically modified material will be implemented for flavourings as well.

The new regulation will define the permitted processes for production of natural flavouring ingredients. Definitions and provisions for the use of ingredients containing BAPs have been renewed. Some additional restrictions for source materials for production of flavouring ingredients will be added. The sales descriptions for flavourings will be revised and some definitions will be added [11].

2.2.3
Current Situation in the USA

Under the terms of the US Food Regulations, flavourings fall under the definition of food additives. The respective definition was implemented in the Federal Food Drug and Cosmetic Act by the Food Additives Amendment of 1958. With this amendment, the general requirement of "safety" became the major topic for food additives.

Flavouring substances which were not covered by one of the two grandfather clauses of the Food Additives Amendment needed either an approval or an evaluation as "generally recognised as safe" (GRAS). Under the supervision of the FDA, several flavouring materials have been evaluated. The permitted components are listed in the Code of Federal Regulation (CFR) Title 21, parts 170–180. Components approved as GRAS are listed in parts 182–184 of the same CFR Title [12].

Later, the US Food and Drug Adminstration (FDA) passed the responsibility for evaluation of the GRAS status for flavouring materials to the Flavour Expert Panel (FEXPAN). This panel of scientists from different related scientific areas evaluates new flavouring substances which are applied for notification. The FEXPAN is not affiliated with the flavour industry but is organised by the US Flavour and Extract Manufacturer's Association (FEMA). In publications currently up to GRAS 22, the positively evaluated flavouring substances are published with name, synonyms, identification number and the average maximum-use levels.

The US Regulations only distinguish between natural and artificial flavourings. The European category "nature-identical" is unknown in the legal definitions. If such substances are synthetically produced, they are classified as artificial flavouring substances in the USA.

For labelling of the final foodstuff, use of the term "natural" is divided into two subcategories. First, flavourings which contain only flavouring ingredients from the named source, the so-called from the named fruit flavourings (FTNF). In this case the name of the source can be used together with the word "natural" and followed by the word "flavoured". If the food contains a flavouring where the flavouring ingredients are natural but not solely from the named source, the additional words "with other natural flavour" (WONF) are required. Smoke flavourings derived from smoked wooden or plant materials are natural in the USA. The same applies for process flavourings prepared with natural raw materials. Only if synthetically produced substances were used for the production of a process flavour, it would be artificial, unless these are non-flavouring substances which are declared separately [13].

2.2.4
Current Situation in Japan

The Japanese Food Regulations are based on the Food Sanitation Law (FSL). The FSL was first enacted in 1947 by the Ministry of Health and Welfare, now the Ministry of Health, Labour and Welfare (MHLW) of Japan [14]. The purpose of the FSL is to prevent the occurrence of health hazards arising from human consumption of food, by making necessary regulations and taking any measure sfor the protection of the health of the people. It enables the MHLW to establish detailed regulations to manage immediately diverse issues related to international food distribution and the need for international harmonisation of food regulations [15].

Flavourings are considered to be food additives according to the principle definition of the FSL. Food additives need an authorisation for use. Article 6 of the FSL mentions the general terms under which the use of a food additive is not permitted in and for food. In the FSL Enforcement Regulations, tables with the list of existing and permitted food additives, including the synthetically derived flavouring substances, are mentioned. The food additives appearing on this list are not subject to article 6 of the FSL [16].

Natural flavouring agents and substances generally provided as food and used as food additives are also not subject to the provisions of article 6 of the FSL. Under the terms of the FSL, a list of "origin of natural flavouring agents" and a list of substances generally provided for eating and drinking as food and used as food additives have been compiled and published by the MHLW. In the list of existing and permitted flavouring substances, only about 84 flavouring substances are mentioned by individual name; the other flavouring ingredients are mentioned only by chemical groups.

These chemical groups are:

- Isothiocyanates (except those generally recognised as highly toxic)
- Indoles and its derivatives
- Ethers
- Esters
- Ketones
- Fatty acids
- Aliphatic higher[1] alcohols
- Aliphatic higher aldehydes (except those generally recognised as highly toxic)
- Aliphatic higher hydrocarbons (except those generally recognised as highly toxic)
- Thioethers
- Thiols (thioalcohols)
- Terpene hydrocarbons
- Phenol ethers
- Phenols

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[1] "Higher" means C6 or more.

- Furfurals and its derivatives (except those generally recognised as highly toxic)
- Aromatic alcohols
- Aromatic aldehydes (except those generally recognised as highly toxic)
- Lactones (except those generally recognised as highly toxic)

Not listed and therefore not permitted are substances from chemical groups like pyrazines, pyridines, amines, amides, or aliphatic lower alcohols, aldehydes and hydrocarbons (C5 and lower) if not mentioned by individual name [17].

The MHLW is currently evaluating several individual flavouring substances not covered by the aforementioned groups but that are of commercial interest. Most of these substances are lower alcohols, aldehydes and pyrazines. As soon as the evaluation has finished, the result will be published and in positive cases the substances will by added to the list of permitted substances.

2.2.5
Global Approach

A major lack in global comparability of flavourings is the difference between the permitted flavouring ingredients . Owing to the difference in the regulations mentioned, a broad range of flavouring substances are only permitted in one region or country. In 2000, the Japan Flavour and Fragrance Materials Association (JFFMA) started a survey with the objective to create a list of all flavouring substances marketed in Japan and to compare them with the EU Register and the US FEMA listed substances. On the basis of the figures for 2001, the FEMA list covered 1,578 substances, the EU Register contained 2,702 substances, whereas 2,577 flavouring substances were reported as being used in Japan.

Comparison with the EU Register showed that 1,800 substances are covered in both lists. Of those, 777 substances were only used in Japan, whereas 902 substances were only mentioned in the EU Register, and of those 640 were not used in Japan and 181 were not permitted for use in Japan. Further, 81 substances from the EU Register are not classified as flavouring substances in Japan [18].

Compared with the FEMA-listed substances, similar results were obtained. A total of 1,182 substances were mentioned in the Japanese survey and the FEMA list. Of those, 1,342 substances were only reported in Japan and 396 substances were only on the FEMA list. In addition, 216 of them had no reported use, 73 were not permitted in Japan and 107 were not classified as flavouring substances [18]. Owing to the fact that the EU Register covered the substances from the FEMA list up to GRAS 21, only a few new substances from the GRAS 22 publication and some substances that were deleted because of no reported use are not implemented in the EU Register in the amended version.

But the comparison with the Japanese survey showed that 749 flavouring substances had reported use in Japan but were neither listed in the FEMA list nor in the EU Register [18].

Such figures indicate the necessity for a global regulatory approach for flavouring material.

The Codex Committee on Food Additives and Contaminants (CCFAC) of the Codex Alimentarius Commission agreed to propose work on the elaboration of a "Codex Guideline for the Use of Flavourings" that establishes safe conditions of use for such substances in foodstuffs. This should lead to globally accepted general requirements for flavourings, including definition, safe use, labelling and specifications. In addition it should provide a reference to the safety evaluations completed by JECFA as a global approach for evaluation and authorisation procedures [19].

2.3
Legal Situation and Natural Flavourings, a Brief Reflection

Most of the regulations on flavourings distinguish between natural derived flavouring components and substances produced synthetically. There are still some differences between the national rules regarding source materials and accepted techniques.

All flavourings considered natural in the EU should also be considered natural in the USA; however, the reverse is not necessarily true. Smoke flavourings and process flavourings are separate categories in the EU, and cannot be used in natural flavours, whereas smoke flavourings as well as process flavourings prepared with natural raw materials are considered natural in the USA. Another important difference between the EU and the USA is the methods allowed to obtain "natural flavouring substances". Under the legal terms of the USA, the naturalness of the starting material defines the status of the resulting product [13]. The EU Flavour Directive defines the staring materials as well as the permitted processes to obtain natural substances or natural preparations [2]. This excludes any type of chemical processing or chemically catalysed process. These differences in definition and handling of natural flavouring materials will be explained using α-ionone as an example.

α-Ionone is an important flavouring substance for a range of fruit flavour systems. In various fruit and plant species α-ionone was found as an almost optically pure *R* enantiomer, whereas the chemical synthesis will lead to a racemic mixture of both enantiomers. The chemical synthesis of α-ionone uses citral, which is condensed with acetone in basic media to the respective pseudo-ionone, followed by cyclisation in acidic media. If now, with this way of production, solely natural citral and natural acetone, derived from fermentation processes, together with natural pH adjusting materials are used, the resulting α-ionone fulfils the US requirements for natural flavouring substances. However the process is still a chemical reaction leading to a catalysed formation of a covalent C–C binding. Therefore the α-ionone derived from such a process will not fulfil the EU definitions for a natural flavouring substance. In the EU this α-ionone is still considered to be a "nature-identical flavouring substance" according to the EU Flavour Directive [2].

But the general goal to differentiate between natural and synthetically derived materials is obvious. This main issues of the flavouring regulations are resumed in the respective rules of the single categories of food products. Many of these regulations permit only the use of natural flavourings for specific types of foodstuffs. Often such products are more highly qualified or many contain the depicting or labelling of a respective source.

Not the general focus on “green chemistry” nor the move towards “natural” or even “organic” sources of food products observed over the last decade in industrial nations has led to this focus on natural flavourings. Most of these regulations focussing on natural flavourings were established long ago. With this long-term history of the respective regulations on flavourings focussing on “renewable” resources, the governments have emphasised the importance of the sensorial impression from the natural sources. This demand led to the current situation that the flavour industry and the respective research institutes have become one of the driving forces in development of new methods using “renewable resources” for the generation of flavouring materials.

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